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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,860	04/16/2002	Peter James Brian Lamb	ADMS-0003	8533
7590	02/22/2005		EXAMINER	
David A Cherry Woodcock Washburn 46th Floor One Liberty Place Philadelphia, PA 19103			GIBSON, KESHIA L	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 02/22/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/031,860

Applicant(s)

LAMB, PETER JAMES BRIAN

Examiner

Keshia Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/24/02 & 2/19/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 8-9, and 14 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rademaker et al. (US 5,397,312).

In regard to Claim 1, Rademaker et al. disclose an applicator for inserting a medicament into a vagina the applicator has an elongate body (Fig. 1) and including a gripping portion 7, an elongate barrel 1 with a passage (extending from chamber 4 to front end of control button 19), and a plunger 2. The barrel 1 extends from the gripping portion 7 (Figs. 1 and 2). A portion of the passage is curved (Figs. 1 and 2, column 2, lines 52-61). The passage extends through the elongate body, has an outlet 3 at the free end of the barrel, and is also configured to receive a nonflowable object or medicament. The plunger 2 can be displaced along the passage to push a medicament in the passage through the outlet 3 into the user's vagina (column 3, line 67- column 4, line 60).

Although Rademaker et al. do not disclose the medicament as cream-type substance, their applicator meets the structural limitations set forth by the claimed invention and is thereof also capable of inserting a nonflowable medicament into the vagina; and, therefore anticipates the claimed invention.

In regard to Claim 8, the passage includes a chamber **4** for receiving a medicament or object (column 2, line 62- column 3, line 5).

In regard to Claim 9, the chamber **4** is spaced from the outlet **3** (Fig. 2). The end edges of the barrel **1** at opening **3** are displaced toward each other to prevent the medicament/object from escaping from the applicator and scraping inner tissue of the vagina during insertion (Figs. 1 ad 2, column 3, lines 6-11).

In regard to Claim 14, the applicator may have a monolithic, integrally moulded body (column 5, lines 13-27). Although Rademaker et al. do disclose that the body may be moulded, it is noted that the method of forming the device is not relevant to the issue of patentability of the device itself. Therefore, the limitation of "integrally moulded" has been given little patentable weight.

3. Claims 3, 10, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Paul et al (US 5,158,535).

In regard to Claim 3, Paul et al. disclose an applicator **10** for insertion of an object into the vagina (abstract; column 3, lines 34-39). The applicator has an elongate body **14**, **16** having an elongate barrel **14**, a gripping portion **20**, a passage (extending from the hollow of enlarged portion **18** through the hollow of the plunger **16**), a nonflowable object **12**, and a plunger **16**. The passage **18** extends through the body **14**, **16**, has an outlet (opening near **28**), and can receive a medicament or object **12** (Figs. 1 and 2). A portion of the passage spaced from the outlet (opening near **28**) is curved in a longitudinal direction (Figs. 1 and 2; column 3, lines 54-66). The plunger **16** is displaced

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along the passage to push a tampon (object) **12** out of the passage through the outlet (opening near **28**) (Figs. 1, 2, and 7; column 6, lines 20-31).

In regard to Claim 10, Paul et al. further disclose that the barrel **14** a longitudinally extending slit (at end **46**) through which a string **13** of a tampon **12** received in the passage can protrude (Figs. 1, 2, and 7; column 6, lines 7-31).

In regard to Claim 15, Paul et al. further disclose that parts (or petals) **28** of the barrel **14**, which are positioned above and below the outlet (opening near **28**) are displaceable toward each other. Paul et al. disclose that the petals are thin, flexible members separated by slits/grooves **30** and are capable of bending radially outward as the tampon **12** is expelled from the barrel **18** (column 4, lines 5-19). If the petals are flexible and capable of being bent outward due to forces being applied from the expulsion of the tampon **12** then it is inherent that the petals **28** are also capable of being bend inward due to the forces being applied due to the insertion of the applicator into the vagina.

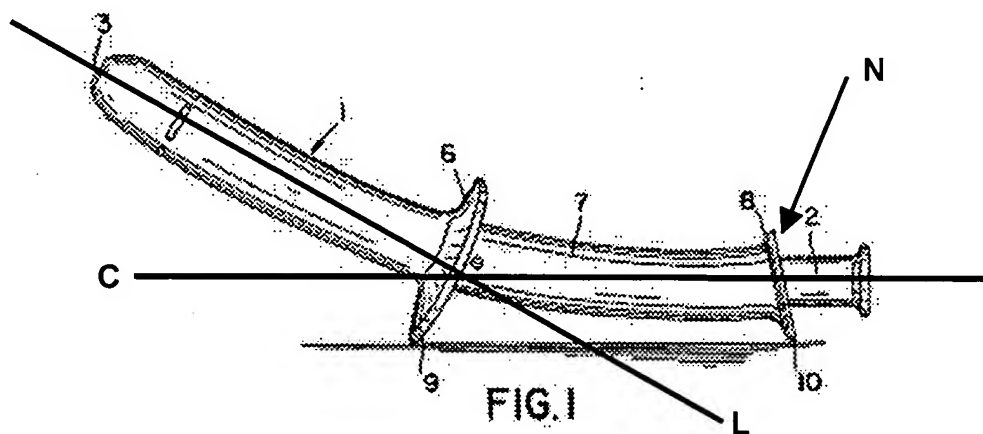
### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rademaker et al.

In regard to Claim 5, Rademaker et al. disclose that the passage has an inlet N (near collar 8; see Figs. 2 and 4 and Fig. A below) remote from its outlet 3. The curved portion of the passage of the passage renders a centrally disposed longitudinal L axis of the barrel and a centrally disposed axis through the inlet N at an obtuse angle (see Fig. A below).



**Figure A.** Examiner's Mark-up of Rademaker et al. Fig. 1 to define axes.

Thus, Rademaker et al. teach that the barrel and the passage are at an obtuse angle relative to each other and also teach that the applicator should be curved so that it follows the nature curvature of the vagina (column 1, lines 33-45; column 2, lines 52-61); but they do not expressly disclose that the obtuse angle created by these axes is between 135 and 170 degrees. Therefore, Rademaker the claimed invention except for the centrally disposed axes of the barrel and the passage being creating an obtuse angle of between 170 to 135 degrees relative to each other. It would have been obvious to one of ordinary skill in the art to have the centrally disposed axes of the barrel and the passage at an obtuse angle at between 170 to 135 degrees relative to each other

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since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regard to Claim 6, as discussed for Claim 5, Rademaker et al. disclose the claimed invention except for expressly disclosing an obtuse angle between the barrel and passage of between 160 and 140 degrees. However, Rademaker et al. do teach that the barrel and passage axes are at an obtuse angle relative to each other. It would have been obvious to one of ordinary skill in the art to dispose the barrel and passage at an obtuse angle of between 160 and 140 degrees relative to each other since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regard to Claim 11, Rademaker et al. disclose the claimed invention except for the barrel having a Shore A hardness between 40 and 80. However, Rademaker et al. do teach that the barrel is to be made from synthetic plastics or polymeric materials (column 4, line 61- column 5, line 12). Therefore, it would have been obvious to one of ordinary skill in the art to provide the barrel with a Shore A hardness of between 40 and 80 since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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6. Claims 2, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rademaker in view of KenKnight (US 5,314,464).

In regard to Claim 2, Rademaker et al. disclose an applicator for inserting a medicament into a vagina the applicator has an elongate body (Fig. 1), an elongate barrel 1 with a passage (extending from chamber 4 to front end of control button 19), and a plunger 2. A portion of the passage spaced from the outlet is curved (Figs. 1 and 2, column 2, lines 52-61). The passage extends through the elongate body, has an outlet 3 at the free end of the barrel, and is also configured to receive a nonflowable object or medicament. The plunger 2 can be displaced along the passage to push a medicament in the passage through the outlet 3 into the user's vagina (column 3, line 67- column 4, line 60). Rademaker et al. do not disclose that the elongate barrel is penile-shaped or roughly triangular in shape.

KenKnight et al. disclose an applicator for inserting an object into a patient's body. The applicator has an elongate body 12 that includes an elongate barrel 26 and a plunger 36, 40 (Fig. 1). The barrel 26 has a penile-shaped or roughly triangular cross-section (Fig. 1). KenKnight et al. teach that this shape prevents inadvertent snagging and other trauma to body tissue during use of the applicator (column 4, lines 5-9). Thus, it would have been obvious to one of ordinary skill in the art to modify the barrel of Rademaker et al. to have a penile shape as taught by KenKnight et al. since doing so would reduce the trauma cause to vaginal tissue during use of the applicator.

In regard to Claim 4, as discussed for Claim 1, Rademaker et al. disclose the claimed invention except for the barrel having a penile, or roughly triangular, shape. As



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discussed for Claim 2, KenKnight et al. disclose an applicator having a barrel with a penile shape in order to reduce or prevent trauma to body tissue during use of the applicator (column 4, lines 5-9). Thus, it would have been obvious to one of ordinary skill in the art to modify the barrel of Rademaker et al. to have a penile shape as taught by KenKnight et al. since doing so would reduce the trauma cause to vaginal tissue during use of the applicator.

In regard to Claim 7, Rademaker et al. disclose the claimed invention except for an outlet end portion of the barrel having the general shape of a glans penis. KenKnight et al. disclose a barrel **26** in the general shape of a glans penis at the end **30, 34** of the applicator (Fig. 1). Again, as discussed for Claims 2 and 4, KenKnight et al. teach that this shape prevents inadvertent snagging and other trauma to body tissue during use of the applicator (column 4, lines 5-9). Thus, it would have been obvious to one of ordinary skill in the art to modify the outlet end of the barrel of Rademaker et al. to have a penile shape as taught by KenKnight et al. since doing so would reduce the trauma cause to vaginal tissue during use of the applicator.

7. Claims 12 and 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rademaker in view of Paul et al.

In regard to Claim 12, Rademaker et al. disclose the claimed invention except for the body **1,7** and the plunger **2** being made of paper or paper pulp to make the device disposable. As discussed for Claim 3, Paul et al. disclose an applicator **10** for insertion of an object into the vagina (abstract, column 3, lines 34-39). The applicator has an elongate body **14, 16** having an elongate barrel **14**, a gripping portion **20**, a passage

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(extending from the hollow of enlarged portion **18** through the hollow of the plunger **16**), a nonflowable object **12**, and a plunger **16**. Paul et al. teach that the applicator **10** may be made of cardboard (paper or paper pulp) in order to make it flushable (disposable) (column 7, lines 1-4). Thus it would have been obvious to one of ordinary skill in the art to modify the applicator body and plunger of Rademaker et al. to be manufactured from paper or paper pulp as taught by Paul et al. since doing so would render the applicator disposable.

In regard to Claim 13, Rademaker et al. disclose the claimed invention except for the body having gripping surfaces, the body being gripped at these gripping surfaces between a thumb, an index finger, and a middle finger of one hand of the user, the middle finger and the index finger touching the body in respective areas, and the body of the applicator oriented such that the areas are in the same horizontal plane and the barrel projects upwardly away from the horizontal plane at an angle between 45 and 10 degrees. Again, Paul et al. disclose an applicator **10** for insertion of an object into the vagina (abstract, column 3, lines 34-39). The applicator has an elongate body **14**, **16** having an elongate barrel **14**, a gripping portion **20**, a passage (extending from the hollow of enlarged portion **18** through the hollow of the plunger **16**), a nonflowable object **12**, and a plunger **16**. Paul et al. teach adding finger-gripping surfaces **34** to the applicator in order to assist the user in holding the applicator **10** (column 5, lines 3-18). Thus, it would have been obvious to one of ordinary skill in the art to modify the body of Rademaker et al. to have gripping surfaces as taught by Paul et al. since doing so would assist the user in holding the applicator.

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In reference to the method of gripping the applicator, it has been held that the prior art inherently performs a claimed method when that prior art meets the structural limitations of the article of the claimed invention and is used in normal and usual operation (see MPEP 2112.02). It is considered normal and usual operation for a user to grasp an applicator, insert it into the vagina, and expel the tampon from the applicator into the vagina all with one hand. Therefore, Rademaker et al. and Paul et al. make obvious the method of the claimed invention.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Waring (US 2,007,626) and Fox et al. (US 5,395,308).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out of the office every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kg 2/16/05

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Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700

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